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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jen SHEEN	Art Unit:	1638
Serial No.:	09/848,806	Examiner:	Cynthia E. Collins
Filed:	May 4, 2001	Customer No.:	21559
Title:	CALCIUM DEPENDENT PROTEIN KINASE POLYPEPTIDES AS REGULATORS OF PLANT DISEASE RESISTANCE		

Mail Stop Appeal
Commissioner for Patents
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APPEAL BRIEF ON APPEAL PURSUANT TO 37 C.F.R. § 41.37

In support of Appellant's Notice of Appeal filed June 28, 2004 (mailed June 24, 2004) of the Office's final rejection mailed on December 24, 2003, submitted herewith is Appellant's Appeal Brief.

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Real Party in Interest

The Real Party in Interest is The General Hospital Corporation, to which all interest in the present application has been assigned by virtue of an Assignment, recorded on April 12, 2002 (Reel/Frame 012814/0365).

Related Appeals and Interferences

There are no pending appeals or interferences related to this case.

Status of Claims

Claims 1-57 are pending. Claims 9 and 17-53 are withdrawn from consideration. Claims 1-8, 10-16, and 54-57 are on appeal.

Status of Amendments

All amendments have been entered and are reflected in the appended claims.

Summary of Claimed Subject Matter

Appellant's invention generally features a method of producing a plant having an increased level of resistance to a disease-causing pathogen, the method includes the steps of: a) providing a plant cell overexpressing a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide (see, for example, page 13 (lines 1-22);

pages 16 (line 10) -24 (line 12), and 26 (line 11) -29 (line 6)), wherein the nucleic acid molecule is selected from the group consisting of (i) a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 (see, for example, Fig. 1) and (ii) a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEQ ID NO:1 (see, for example, Fig. 1, page 5 (lines 7-16), and page 13 (line 23) – page 16 (line 9); and b) regenerating a plant from the plant cell, wherein the CDPK polypeptide is expressed in the plant, increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant (see, for example, pages 24 (line 13) -29 (line 6)).

Grounds of Rejection to be Reviewed on Appeal

This appeal presents five issues:

I. Whether the Office erred in rejecting claims 1-7, 10-16, 54, and 56 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification;

II. Whether the Office erred in rejecting claims 1-8, 10-16, and 54-57 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention;

III. Whether the Office erred in rejecting claim 10 under 35 U.S.C § 112, second paragraph;

IV. Whether the Office erred in rejecting claims 1-8, 10-16, and 54-57 under 35 U.S.C. § 102(b) as being anticipated by Sheen (WO 98/26045); and

V. Whether the Office erred in rejecting claims 1-8, 10-16, and 54-57 under 35 U.S.C. § 103(a) as being obvious.

Argument

I. Applicants' Specification Provides a Written Description of the Claimed Invention

Claims 1-7, 10-16, 54 and 56 were finally rejected under 35 U.S.C. § 112, first paragraph, for lack of a written description. This rejection should be reversed.

The adequate written description requirement of 35 U.S.C. § 112, ¶ 1 provides that

> the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...

The written description requirement serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material." *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). In order to meet the written description requirement, the applicant need not utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d

1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989) (citation omitted). Stated another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

Independent claim 1 requires providing a plant cell overexpressing a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide, wherein the nucleic acid molecule is selected from the group consisting of (i) a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 and (ii) a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEQ ID NO:1 [CDPK2 of *Arabidopsis*.].

As an initial matter, Appellant points out that, with respect to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1, there can be no question that the written description requirement is satisfied, as SEQ ID NO: 1 is presented in Appellant's specification.

In response to the Office's assertion that the specification does not describe the specific structural features that are correlated with the function of increasing the level of resistance to a disease-causing pathogen, Appellant notes that the sequences used in the claimed methods encode calcium dependent protein kinase (CDPK) polypeptides, and such calcium dependent protein kinase activity is clearly a functional limitation that distinguishes polypeptides used in the methods from other polypeptides. As stated in the

Written Description Guidelines (66 FR 1106),

> [f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, **functional characteristics alone or coupled with a known or disclosed correlation between structure and function**, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient (emphasis added.).

Accordingly, polypeptides used in the claimed methods are distinguished from other polypeptides by both the structural characteristic of having at least 80% sequence identity to SEQ ID NO:1 and by the specific functional characteristic of having calcium dependent protein kinase activity. As clear distinguishing characteristics that are shared by the claimed proteins are disclosed in Appellant's specification, this rejection should be reversed.

II. Appellant's Specification Enables the Claimed Invention

Claims 1-8, 10-16, and 54-57 stand finally rejected under § 112, first paragraph based on the assertion that the teaching of Appellant's specification is not commensurate in scope with the present claims. The rejection essentially turns on the assertions that practicing the claimed method requires "undue experimentation in selecting which sequences to express and under what conditions to obtain resistance to a particular diseased-causing pathogen, rather than in employing techniques that could be used to

identify plants to overexpress a nucleic acid or that exhibit disease resistance." (Office Action mailed December 24, 2004, page 6). This rejection should be reversed.

Appellant directs the Office's attention to the enablement standard as articulated in *In re Wands*, 858 F.2d. 713, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Wands involved the identification of monoclonal antibodies of a specific isotype directed against particular antigens. The nature of this technology involved screening hybridomas to identify those that secreted antibody having the desired characteristics. Identifying genes having the desired characteristics according to the present invention, as in *Wands*, involves straightforward and routine screening methods. Moreover, methods for overexpressing a gene in a plant were well known at the time of Appellant's invention. In this respect, at page 19 (line 18), Appellant teaches the cauliflower mosaic virus promoters (35S and 19S), which confer high levels of expression in plant tissues. In addition, the specification teaches using a duplicated cauliflower mosaic virus promoter to achieve overexpression. (See, also, Appellant's specification at page 13, where, it is taught that CDPK2 was expressed under the control of the 35S promoter.) There can be no question that Appellant's specification teaches methods of overexpressing a gene in a plant cell.

Furthermore, as was stated in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Identifying genes expressing polypeptides having 80% identity to SEQ ID

NO.:1 for practicing the claimed invention cannot constitute undue experimentation, especially given Appellant's teaching of the transient protoplast expression system. Furthermore, given Appellant's teachings and results, Appellant's specification cannot be found as failing to enable the claimed invention when the techniques required to practice the invention are disclosed in the specification and available to those skilled in the art. See *In re Wands, 858 F.2d* 731, 740, 8 USPQ2d 1400, 1406; *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982). Finally, it is improper to find that screening of plants having resistance to a pathogen is "undue" simply because it requires some trial and error, *W.L. Gore & Assoc. v. Garlock, Inc.* 721 F.2d 1540, 1557, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983). This is true even when the experimentation is needed to weed out inoperative embodiments. *Atlas Powder v. E.I. DuPont deNemours*, 750 F.2d 1569, 1576-77, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984). The enablement rejection should therefore be reversed.

III. "Consists essentially of" Is Not Indefinite

Claim 10 was deemed indefinite in the recitation of "consists essentially of." The Office contends "it is unclear what would not materially affect the CDPK polypeptide used." Appellant points out that the claim simply refers to a CDPK polypeptide that consists of the CDPK protein kinase domain itself, absent other portions of the full-length molecule. Appellant points out that the phrase "consists essentially of" is a transition

phrase commonly used to signal a partially open claim. Typically, "consists essentially of" precedes a list of ingredients in the process claim. By using the term "consists essentially of," applicant is signaling that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. One skilled in the art would appreciate what is meant and encompassed by the phrase "consists essentially of CDPK protein kinase domain," and this basis for the rejection of claim 10 may be withdrawn. Claim 10 is therefore clear and the indefiniteness rejection must be reversed.

IV. WO 98/26045 Does Not Anticipate the Claimed Invention

The case law is clear that, to anticipate a claim, a prior art reference must disclose, either expressly or inherently, all of the limitations of the claim. *Kalman v. Kimberley-Clark Corp.*, 713 F.2d 760, 218 U.S.P.Q. 781 (Fed. Cir. 1983).

In maintaining the anticipation rejection in view of WO 98/26045, the Office states:

> The [anticipation] rejection is maintained because Sheen teaches the same method as set forth in the rejected claims, namely a) providing a plant cell overexpressing a nucleic acid encoding a CDPK of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1, and b) regenerating a plant, wherein the CDPK polypeptide is expressed in said plant. The specification is not relied upon to support the argument of inherency, and no additional evidence in the prior art in support of the assertion that expression of a nucleic acid encoding a calcium dependent protein kinase as set forth in claim 1 would increase the level of resistance of a plant to a disease-causing pathogen is needed. Because the rejected claims set forth no positive method steps that would distinguish the claimed method from the method

> disclosed in the prior art, the method taught by Sheen, being the same as the method set forth in the rejected claims, must necessarily increase the level of resistance of a plant to a disease-causing pathogen. (Office Action mailed December 24, 2003, pages 7-8.)

Appellant's claims requires "regenerating a plant from said plant cell, wherein said CDPK polypeptide is expressed in said plant, increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant." Applicant notes that WO 98/26045 teaches the discovery of using a CDPK to protect a plant against stresses such as drought, salinity, cold, and heat. WO 98/26045 is silent on whether CDPK regulates disease resistance genes, and there is no evidence indicating that disease resistance is necessarily present. Contrary to the Office's assertion that "no positive method steps that would distinguish the claimed method from the method disclosed in the prior art," Appellant points out, as stated above, that the claims require "increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant." WO 98/26045 does not teach such a method. The anticipation rejection has been maintained in error; it should be reversed.

V. Lusso and Urao, In Combination, Do Not Suggest the Claimed Invention

To establish a *prima facie* case of obviousness under § 103, the Examiner must demonstrate that the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious, at the time the invention was

made, to a person having ordinary skill in the art. *See* 35 U.S.C. § 103(a) (Supp. III 1997); *In re Dembiczak*, 175 F.3d 994, 998, 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999), *abrogated on other grounds by In re Gartside*, 203 F.3d 1305, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000). Whether or not a claimed invention would have been obvious is a "legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Id.*

Claims 1-8, 10-16, and 54-57 feature methods of producing a plant having an increased level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant. These claims stand rejected under 35 U.S.C. § 103 as obvious over Lusso et al. (WO 99/02655, published 21 January 1999) in view of Urao et al. (SPTREMBL Accession No. Q39016, 01 November 1996, Calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana*) based on the Office's assertion that:

> **Given the success of Lusso et al. in producing a plant having increased resistance to a disease-causing plant pathogen by regenerating a plant from a plant cell that overexpresses a polynucleotide encoding a soybean calcium-dependent protein kinase polypeptide**, and given the further teaching that their method can be practiced using a polynucleotide that hybridizes to or has at least 70% sequence identity with their disclosed polynucleotide, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to practice the method disclosed by Lusso et al. with any polynucleotide that encodes a calcium-dependent protein kinase and that hybridizes to or has at least 70% sequence identity with their disclosed polynucleotide, such as the polynucleotide encoding the calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana* taught by Urao et al., without any surprising or unexplained results. Accordingly, one skilled in the art would have been

> motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary (emphasis added). (Office Action mailed December 24, 2003, pages 9-10.)

Contrary to the Examiner's assertion that "given the success in producing a plant having increased resistance to a disease-causing pathogen, Lusso, in fact, fails to provide any evidence that a plant overexpressing a CDPK gene is resistant to a disease-causing pathogen. Lusso therefore does not teach what the Office asserts and does not suggest the claimed invention.

In addition, the secondary reference, Urao, fails entirely to remedy the deficiencies of Lusso. Urao merely describes the *Arabidopsis* CDPK polypeptide sequence. Urao does not provide the skilled artisan with the information, requisite motivation, or expectation of success required to produce a plant having an increased level of resistance to a disease-causing pathogen.

Appellant was the first to demonstrate that expression of CDPK polypeptide in a plant activated several well-defined early pathogen responsive genes as evidenced by Appellant's specification (see, for example, pages 11-13). Indeed, Appellant has provided *in vivo* results, using a protoplast system, that the *Arabidopsis* CDPK2 is the first plant gene to be directly involved in the activation of such early pathogen responsive genes in a functional assay. CDPK is therefore an example of a positive regulator, useful for controlling pathogen signal transduction in plants. The references cited by the Office

uniformly fail to recognize these key insights.

The obviousness rejection is in error, and should be reversed.

CONCLUSION

Appellant respectfully requests that the rejection of claims 1-8, 10-16, and 54-57 be reversed.

Enclosed is a check for $250.00 in payment of the fee required by 37 C.F.R. § 41.20(b)(2). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Claims Appendix

Claim 1 (previously presented): A method of producing a plant having an increased level of resistance to a disease-causing pathogen, said method comprising the steps of:

a) providing a plant cell overexpressing a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide, wherein said nucleic acid molecule is selected from the group consisting of

(i) a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 and

(ii) a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEQ ID NO:1; and

b) regenerating a plant from said plant cell, wherein said CDPK polypeptide is expressed in said plant, increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant.

Claim 2 (original): The method of claim 1, wherein said plant cell is a dicotyledonous plant cell.

Claim 3 (original): The method of claim 2, wherein said dicotyledonous plant cell is a cruciferous plant cell.

Claim 4 (original): The method of claim 1, wherein said plant cell is a monocotyledonous plant cell.

Claim 5 (previously presented): The method of claim 1, wherein said disease-causing pathogen is a plant pathogen.

Claim 6 (previously presented): The method of claim 1, wherein said plant cell is a transgenic plant cell.

Claim 7 (original): The method of claim 6, wherein said transgenic plant cell comprises a transgene that expresses a nucleic acid molecule encoding a CDPK polypeptide.

Claim 8 (previously presented): The method of claim 7, wherein said CDPK polypeptide is the polypeptide of SEQ ID NO:1.

Claim 9 (withdrawn): The method of claim 7, wherein said CDPK polypeptide is CDPK4.

Claim 10 (previously presented): The method of claim 7, wherein said CDPK polypeptide consists essentially of the CDPK protein kinase domain.

Claim 11 (original): The method of claim 7, wherein said CDPK polypeptide is a constitutively-active CDPK polypeptide.

Claim 12 (original): The method of claim 7, wherein said transgene ectopically expresses said nucleic acid molecule encoding said CDPK polypeptide.

Claim 13 (original): The method of claim 7, wherein the transgene comprises an inducible promoter.

Claim 14 (original): The method of claim 7, wherein the transgene comprises a constitutive promoter.

Claim 15 (original): The method of claim 7, wherein the transgene comprises a tissue-specific promoter.

Claim 16 (original): The method of claim 7, wherein said nucleic acid molecule is either derived from *Arabidopsis* or is an ortholog thereof.

Claim 17 (withdrawn): A method of conferring pathogen resistance on a plant, the method comprising the steps of:

a) crossing a pathogen resistant plant prepared by the method of claim 1 with a plant having susceptibility to a pathogen;

b) recovering reproductive material from the progeny of the cross; and

c) growing pathogen resistant plants from the reproductive material.

Claim 18 (withdrawn): The method of claim 17, said method further comprising repetitively crossing the pathogen resistant progeny with disease susceptible plants, and selecting for expression of pathogen resistance.

Claim 19 (withdrawn): A method for breeding pathogen resistance into plants, said method comprising:

a) selecting a plant that expresses a nucleic acid molecule encoding a CDPK polypeptide; and

b) selecting pathogen resistant progeny.

Claim 20 (withdrawn): The method of claim 19, wherein said plant is a transgenic plant.

Claim 21 (withdrawn): The method of claim 20, wherein said transgenic plant comprises a transgene that expresses a nucleic acid molecule encoding a CDPK polypeptide.

Claim 22 (withdrawn): The method of claim 21, wherein said transgene ectopically expresses a nucleic acid molecule encoding said CDPK polypeptide.

Claim 23 (withdrawn): The method of claim 21, wherein said CDPK polypeptide is CDPK2.

Claim 24 (withdrawn): The method of claim 21, wherein said CDPK polypeptide is CDPK4.

Claim 25 (withdrawn): The method of claim 21, wherein the CDPK polypeptide consists essentially of the protein kinase domain.

Claim 26 (withdrawn): The method of claim 21, wherein the CDPK polypeptide is a constitutively-active CDPK polypeptide.

Claim 27 (withdrawn): A non-naturally occurring plant that expresses a nucleic acid molecule encoding a CDPK2 polypeptide.

Claim 28 (withdrawn): The non-naturally occurring plant of claim 27, said plant comprising a transgene that includes a nucleic acid molecule encoding a CDPK2 polypeptide, expression of said nucleic acid molecule being under the control of an expression control region that is functional in a plant cell.

Claim 29 (withdrawn): The non-naturally occurring plant of claim 28, wherein the nucleic acid molecule encoding said CDPK2 polypeptide is derived from a plant.

Claim 30 (withdrawn): The non-naturally occurring plant of claim 28, wherein the CDPK2 polypeptide consists essentially of the protein kinase domain.

Claim 31 (withdrawn): The non-naturally occurring plant of claim 28, wherein said transgene that encodes said CDPK2 polypeptide is either derived from *Arabidopsis* or is an ortholog thereof.

Claim 32 (withdrawn): The non-naturally occurring plant of claim 27, wherein said plant is a dicotyledonous plant

Claim 33 (withdrawn): The non-naturally occurring plant of claim 27, wherein said plant is a monocotyledonous plant.

Claim 34 (withdrawn): A seed from the non-naturally occurring plant of claim 27.

Claim 35 (withdrawn): A cell from the non-naturally plant of claim 27.

Claim 36 (withdrawn): A non-naturally occurring plant that expresses a nucleic acid molecule encoding a CDPK4 polypeptide.

Claim 37 (withdrawn): The non-naturally occurring plant of claim 36, said plant comprising a transgene that includes a nucleic acid molecule encoding a CDPK4 polypeptide, expression of said nucleic acid molecule being under the control of an expression control region that is functional in a plant cell.

Claim 38 (withdrawn): The non-naturally occurring plant of claim 36, wherein the nucleic acid molecule encoding said CDPK4 polypeptide is derived from a plant.

Claim 39 (withdrawn): The non-naturally occurring plant of claim 36, wherein the CDPK4 polypeptide consists essentially of the protein kinase domain.

Claim 40 (withdrawn): The non-naturally occurring plant of claim 36, wherein the CDPK4 polypeptide is a constitutively-active CDPK4 polypeptide.

Claim 41 (withdrawn): The non-naturally occurring plant of claim 36, wherein said transgene that encodes said CDPK4 polypeptide is either derived from *Arabidopsis* or is an ortholog thereof.

Claim 42 (withdrawn): The non-naturally occurring plant of claim 36, wherein said plant is a dicot.

Claim 43 (withdrawn): The non-naturally occurring plant of claim 36, wherein said plant is a monocot.

Claim 44 (withdrawn): A seed from the non-naturally occurring plant of claim 36.

Claim 45 (withdrawn): A cell from the non-naturally occurring plant of claim 36.

Claim 46 (withdrawn): A vector comprising an expression control region functional in plant cells operably linked to a nucleic acid molecule encoding a CDPK4 polypeptide.

Claim 47 (withdrawn): A vector of claim 46 wherein the CDPK4 polypeptide consists essentially of the protein kinase domain.

Claim 48 (withdrawn): The vector of claim 46 wherein the nucleic acid molecule encoding said CDPK4 polypeptide or protein kinase domain is derived from a plant.

Claim 49 (withdrawn): The vector of claim 46, wherein nucleic acid molecule encoding said CDPK4 polypeptide is a constitutively-active CDPK4 polypeptide.

Claim 50 (withdrawn): The vector of claim 46 wherein said nucleic acid molecule that encodes said CDPK4 polypeptide is either derived from *Arabidopsis* or is an ortholog thereof.

Claim 51 (withdrawn): A cell comprising the vector of claim 46.

Claim 52 (withdrawn): The cell of claim 51, wherein said cell is a plant cell.

Claim 53 (withdrawn): The cell of claim 51, wherein said cell is a prokaryotic cell.

Claim 54 (previously presented): The method of claim 1, wherein said nucleic acid molecule is a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEQ ID NO:1.

Claim 55 (previously presented): The method of claim 54, wherein said nucleic acid molecule encodes the polypeptide of SEQ ID NO:1.

Claim 56 (previously presented): The method of claim 7, wherein said nucleic acid molecule is a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEQ ID NO:1.

Claim 57 (previously presented): The method of claim 56, wherein said nucleic acid molecule encodes the polypeptide of SEQ ID NO:1.